

# FINAL DEGREE PROJECT

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## **Major variables influencing correct antibiotic prescription by primary care physicians in acute pharyngitis: a cross-sectional study**

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Girona, January 2014

*A en Gabriel Coll de Tuero, per fer-me estimar el món de la Medicina de Família i de la recerca, i per ensenyar-me conceptes que de ben segur, mai oblidaré.*

*Girona, January 2014*

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## 1. Abstract

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**Objectives:** To analyse which are the main variables that influence primary care professionals, in the prescription of antibiotics in patients with acute pharyngitis. To analyse which is the diagnosis pattern used by primary care professionals towards acute pharyngitis. To recognize the clinical and analytical criteria that primary care professionals use, to determine antibiotic treatment in acute pharyngitis. To identify the main clinical variables related with the prescription of antibiotics by primary care professionals, in acute pharyngitis treatment.

**Design:** Cross-sectional study

**Participants:** 165 primary care professionals from the Sanitary Region of Girona not attending paediatric patients and randomly selected from 29 ABS managed by two of the main health care providers: Insitut Català de la Salut (ICS) and Institut d'Assistència Sanitària (IAS)

**Main outcome measures:** Each participant will fill out a questionnaire with personal and workplace questions, as well as about knowledge and attitude in front of the acute pharyngitis caused by group A streptococci. They will also answer 4 clinical questions about correct treatment and diagnosis of acute pharyngitis caused by group A streptococci.

**Keywords:** acute pharyngitis; group A streptococci; variables influencing physicians; questionnaire; primary care; influencing factors; perceptions and attitudes.

## **2. Introduction**

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### **2.1. Definition**

Acute pharyngitis is a diffuse inflammatory process that affects the pharyngeal lymphoid follicles. However, due to its anatomical proximity, it normally also produces inflammation of other structures such as adjacent mucous, tonsils, uvula or soft palate <sup>(1,2)</sup>.

This is the main reason why there are often divergences between different authors when naming this process, and so it could be found as acute pharyngitis, tonsillitis or pharyngotonsillitis, interchangeably <sup>(3)</sup>. However, most of the scientific articles use the term acute pharyngitis, reason why we also used it during the drafting of this protocol.

### **2.2. Epidemiology**

Acute pharyngitis accounts for more than four millions of visits to primary care centres in Spain, becoming one of the most common causes for which patients go to the doctor <sup>(1,4)</sup>. Furthermore, when talking about respiratory tract infections rates in Spain, acute pharyngitis is the second illness in frequency, just preceded by the common cold <sup>(5)</sup>.

### **2.3. Classification**

From a clinical point of view, acute pharyngitis could be divided into three different groups: unspecific, specific and as a systematic manifestation of other processes. Although all three are very relevant, it is unspecific acute pharyngitis, which turns out to be the more important one not only for this study but also for its frequency in daily clinical practice <sup>(1,2)</sup>.

Unspecific acute pharyngitis in turn has been divided into two types: red pharyngitis also called catharral acute pharyngitis and normally associated with a viral etiology, and white pharyngitis also known as acute follicular tonsillitis and commonly related with a bacterial pathogen. Although this is a good classification it is not very used because it not always corresponds with reality, since both etiologies can cause both processes <sup>(1)</sup>.

### **2.4. Etiology**

Even though acute pharyngitis could have different etiologies, including some non infectious causes such as tobacco or chemical products, an 80% of cases are viral, being the rhinovirus the main pathogen <sup>(1,3,4)</sup>.

However, bacterial causes are also very important, being the Lancefield group A streptococci the most common <sup>(6)</sup>. This group produces 5 to 10 percent of the acute pharyngitis in adults, a percentage that is exceeded till 15 to 30 percent in children <sup>(4)</sup>. Furthermore, its different therapeutically approach and clinical consequences, such as suppurative and non- suppurative complications, are one of the main reasons why there is a special interest on its correct diagnosis and why so many studies regarding this have been done <sup>(1)</sup>.

## 2.5. Diagnosis

In 1981, Centor et. al created the first clinical decision score for the suspicion of group A streptococci acute pharyngitis, called Centor criteria, which is still very used. These criteria consist of four variables such as tonsillar exudates, swollen tender anterior cervical nodes, lack of cough and fever history over 38,3°C <sup>(7)</sup>. Each one of these items has a different sensitivity (S), specificity (SPC), positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (LR+) and negative likelihood ratio (LR-), which determine their capacity to predict infection by group A streptococci. All this data is reflected in the following table:

Signs and symptoms	S	SPC	PPV	NPV	LR+	LR-
Tonsillar exudates	85,3% (69,9-93,6)	53,8% (44,3-63,0)	37,2% (27,3-48,3)	91,9% (82,5-96,5)	1,85 (1,44-2,37)	0,27 (0,12-0,63)
Swollen tender anterior cervical nodes	73,5% (56,9-85,4)	27,4% (19,8-36,5)	24,5% (17,2-33,7)	76,3% (60,8-87,0)	1,01 (0,80-1,28)	0,97 (0,51-1,84)
Lack of cough	70,6% (53,8-83,2)	45,3% (36,1-54,8)	29,3% (20,5-39,9)	82,8% (71,1-90,4)	1,29 (0,98-1,70)	0,65 (0,37-1,15)
Fever (>38,3°C)	73,5% (56,9-85,4)	57,5% (48,0-66,5)	35,7% (25,5-47,4)	87,1% (77,3-93,1)	1,73 (1,28-2,34)	0,46 (0,25-0,83)

*\*Confidence interval of 95% exposed in brackets*

*Source:* Marín Cañada J, Cubillo Serna A, Gómez-Escalonilla Cruz N, de la Iglesia JG, Benito Ortiz L, Reyes Fernández MN. ¿Es posible el diagnóstico clínico de la faringoamigdalitis estreptocócica? Aten Primaria 2007;39(7):361-5.

The isolated presentation of each one of the signs and symptoms has a positive likelihood ratio less than 3 and a negative likelihood ratio higher than 0.3, which would indicate that by themselves the different signs and symptoms have little interest in the diagnostic of acute pharyngitis caused by group A streptococci. Moreover, the negative predictive values are elevated which informs us that in absence of these signs and symptoms makes it highly unlikely that acute pharyngitis is caused by group A streptococci <sup>(8)</sup>.

Regarding the predictive capacity resulting from the combination of the different items specified above, the results were:

Items number	S	SPC	PPV	NPV	LR+	LR-
1	97,1% (85,1-99,5)	8,5% (4,5-15,4)	25,4% (18,7-33,5)	90,0% (59,6-98,2)	1,06 (0,90-1,11)	0,35 (0,05-2,59)
2	91,2% (77,0-97,0)	26,4% (19,0-35,5)	28,4% (20,8-37,5)	90,3% (75,1-96,7)	1,24 (1,06-1,45)	0,33 (0,11-1,03)
3	76,5% (60,0-87,6)	62,3% (52,8-70,9)	39,4% (28,5-51,5)	89,2% (80,1-94,4)	2,03 (1,49-2,76)	0,38 (0,20-0,71)
4	38,2% (23,9-55,0)	86,8% (79,0-92,0)	48,1% (30,7-66,0)	81,4% (73,3-87,5)	2,89 (1,51-5,54)	0,71 (0,53-0,96)

*\*Confidence interval of 95% exposed in brackets*

*Source:* Marín Cañada J, Cubillo Serna A, Gómez-Escalonilla Cruz N, de la Iglesia JG, Benito Ortiz L, Reyes Fernández MN. ¿Es posible el diagnóstico clínico de la faringoamigdalitis estreptocócica? *Aten Primaria* 2007;39(7):361-5.

High negative predictive values for a total score of 4 determine that is 3 times more likely to be an infection by a group A streptococci rather than if the patient has just 1 item. Furthermore the positive predictive values determine that although 4 items are present, in a 48,1% the cause will be streptococcal. For this reason, it is considered that Centor criteria are mostly useful for rule-out patients without acute pharyngitis caused by group A *Streptococcus* rather than to diagnose them <sup>(8,9)</sup>.

Some years later, in 1998, McIsaac et al. made a review of Centor criteria that included age as a variable influencing the prediction of clinical infection by group A streptococci, considering a higher risk for children younger than 15 years old (1 point) and a lower risk for seniors over 45 years old (-1 point), adopting a punctuation ranging from 0 to 4. In this Canadian study, data concerning risk of streptococcal infection depending on the number of items present, were slightly modified in relation with Centor study and the probability of group A streptococcal infection with total scores up to 4 was of 38-63% <sup>(9,10)</sup>.

Centor score was again modified and adapted in 2004, and although the items were not changed, the estimated risk of group A *Streptococcus* infection was updated, estimating a risk of 51-53% in scores up to 4 <sup>(9,11)</sup>. Finally, in 2012 an article was published comparing these two scores and concluding that both were useful, attributing a higher risk of possible infection by group A streptococcus for higher scores in the two scales <sup>(12)</sup>. However as it is explained, all these criteria are only predictors of possible infections by group A streptococci and not a confirmation diagnostic tool, which give them a low validity <sup>(3,7,13)</sup>.

For this reason, guidelines worldwide talk about throat culture and rapid antigen test (RAT) as the main confirmation diagnostic methods. Firstly, they consider throat culture as the gold standard technique for the detection of group A streptococci, with a sensitivity and specificity of 99-100%. Nonetheless, they talk about a long delay in obtaining the results (18-24h or more) and there is also a discussion about the re-examination of the negative cultures in order to increase the sensitivity of the test <sup>(3,9,11)</sup>.

On the other hand, rapid antigen test (RAT) is also an interesting and fast method in the detection of group A streptococci, that consists in obtaining samples of the pharyngeal wall with a swab, which is lately reacted with a streptococcal antibodies reagent <sup>(3)</sup>. Although there are different types of RATs, all the studies concluded with almost the same information when evaluating the different tests: high specificity of more than 95% and a sensitivity of around 60 and 96%, negative predictive values ranged between 93 and 97% and positive predictive values between 77 and 97%, and a negative likelihood ratio of 0,10 and a positive likelihood ratio of 0,85 <sup>(9,13-17)</sup>. All this information means that RATs are good tests for the detection of group A streptococcal infections, with a low chance of obtaining false positives, which allow the physicians to take therapeutic decisions more quickly <sup>(18)</sup>.

However, RAT is strongly influenced by the experience of the examiner that must know the exact location where to take samples in order to make it effective. Also, the performance of this test depends on the patient's signs and symptoms, which will be oriented by the use of Centor criteria, as explained above. This means that with a higher pre-test probability, its sensitivity will clearly increase, generating a spectrum bias. It is also very important not to forget, that RAT only detects group A streptococci cases, which means that acute pharyngitis caused by other Lancefield groups will be not detected and consequently will be not treated with antibiotics <sup>(14,19)</sup>.

For all these reasons, different worldwide guidelines have different recommendations regarding the use of RAT, although all them say that it is a good tool for diagnosis in susceptible patients with clinical features of streptococcal infection determined by Centor criteria. Spanish manuals and American guidelines, recommend the use of RAT in patients with 2 or more Centor criteria, while the European Society for Clinical Microbiology and Infectious Disease recommend it in patients with 3 or 4 Centor criteria <sup>(9,13,20)</sup>.



## 2.6. Complications

Acute pharyngitis caused by group A streptococci is also characterized by the possibility of developing complications that could be suppurative or non-suppurative. Among the most frequent suppurative complications are the peritonsillar and retropharyngeal abscesses as well as sinusitis, otitis media, mastoiditis and cervical lymphadenitis. These complications are basically produced by the dissemination of the infection to the surrounding structures. On the other hand, non-suppurative complications such as rheumatic fever, acute post streptococcal glomerulonephritis and post streptococcal reactive arthritis are immunologically mediated processes <sup>(3)</sup>.

Is important to say that of all these complications, the most important one is rheumatic fever, because of its high morbidity and mortality, although all the others are relevant. Furthermore, it is a preventable complication if an antibiotic treatment is administered in the early days after the pharyngeal symptomatology is detected <sup>(3,21)</sup>.

However, recent studies have demonstrated that acute pharyngitis complications (suppurative and non-suppurative) in primary care are uncommon. Although it has been confirmed that earache and tonsillar inflammation predict the development of complications in a limited way, it is also well known that most of the complications occur in absence of either variable. Furthermore, these studies show that the scores used to asses risk of bacterial infection such as Centor criteria, are not at all useful in predicting complications <sup>(22)</sup>.

## 2.7. Treatment

Acute pharyngitis caused by group A streptococci is normally solved without the need for antibiotic treatment after a few days, except for some cases <sup>(13)</sup>.

Some guidelines recommend the prescription of antibiotics such as penicillin V twice or three times daily for 10 days, amoxicillin once daily for 10 days or first-generation cephalosporin's, clindamycin, clarithromycin or azithromycin in cases of penicillin-allergic, to patients who have a total score equal or higher than 3 in Centor criteria, or when the throat culture or RAT are positive for group A streptococci. Is also pointed out that analgesics such as NSAID can be used to relieve sore throat, if that is necessary <sup>(9,13,23)</sup>.

However, despite guidelines recommendations and the fact that in 80 % of cases the cause is viral, acute pharyngitis is one of the main infectious disease for which doctors prescribe

antibiotics. It is estimated that although just in a 60% of cases, bacterial etiology is suspected, primary care physicians prescribe antibiotics in 85% of the cases <sup>(1)</sup>. Furthermore, a Cochrane review suggests that benefits obtained from the use of antibiotics are very low, reducing the symptomatology only 16 hours when compared with placebo. This study also points out, that the use of antibiotics in order to reduce the risk of complications is not appropriate since, as I already mentioned, these are very infrequent nowadays <sup>(24)</sup>.

All this information leads us to think that there is an incorrect antibiotic prescription, which is a serious public health problem due to the high rates of antibiotic resistances as well as the great possibility of adverse reactions that antibiotics could generate <sup>(1,4)</sup>.

### **3. Justification**

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As can be appreciated, acute pharyngitis caused by group A Streptococcus, despite being one of the main causes for consultation in primary care, still generates strong discrepancies between clinical practice guidelines and studies, especially in relation to diagnosis and treatment. The lack of consensus in relation to clinical decision score for suspicion of group A Streptococcus acute pharyngitis and RAT use, directly influences the final treatment decision that will take place, which as it was seen is much higher than would be expected <sup>(1)</sup>.

Some studies also suggest that there are many other variables that influence the final antibiotic prescription by primary care physicians <sup>(1,4)</sup>, such as biological features of the professionals as well as their knowledge and attitudes towards these infectious process or work place characteristics, without forgetting the individual characteristics of patients attending the consultation <sup>(25-27)</sup>. However, none of these studies focuses concretely on investigating which are the main causes that influence doctors on this over prescription.

For this reason, we have decided to carry out this study in which we will analyse the major variables that influence primary care professionals in the over prescription of antibiotics in patients with group A streptococci acute pharyngitis by using a questionnaire, in order to be able to in the future present solutions to what could be a serious public health problem.

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## **5. Hypothesis**

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### **Main hypothesis**

- There are differences in the correct antibiotic prescription by the primary care professionals in the treatment of acute pharyngitis

### **Secondary hypothesis**

- There is heterogeneity among primary care professionals, towards the use of major diagnostic strategies in acute pharyngitis that may influence the final treatment with antibiotics.
- There are a number of variables, independent from clinical criteria acquired by primary care professionals that influence the final treatment decision with antibiotics, in acute pharyngitis cases

## 6. Objectives

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### Main objective

- Analyse which are the main variables that influence primary care professionals, in the prescription of antibiotics in patients with acute pharyngitis.

### Secondary objective

- Analyse which is the diagnosis pattern used by primary care professionals towards acute pharyngitis
- Recognize the clinical and analytical criteria that primary care professionals use, to determine antibiotic treatment in acute pharyngitis.
- Identify the main clinical variables related with the prescription of antibiotics by primary care professionals, in acute pharyngitis treatment.



## 7. Methodology

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### 7.1. Study design: Cross sectional study

### 7.2. Population

The target population of this study are the primary care professionals not attending paediatric patients and working in the sanitary region of Girona, more concretely in 2 of the 7 public healthcare providers.

### 7.3 Sample selection

The Sanitary Region of Girona has an extension of 5742km<sup>2</sup>, a total number of 854.142 inhabitants and a total population density of 146,88 inhabitants/km<sup>2</sup> distributed in 218 municipalities. The Sanitary Region of Girona it is composed by 7 sanitary sectors coinciding with its 7 counties (la Selva, Ripollès, Pla de l'Estany, Gironès, Garrotxa, Baix Empordà and Alt Empordà) <sup>(28)</sup>.

A Àrea Bàsica de Salut (ABS) is defined as a territory, with its population, that is attended by a primary care team composed by primary care physicians, paediatricians, nurses, social workers and administrative staff. Girona counties have 35 ABS managed by 7 different healthcare providers, and a total number of primary care professionals of 482.

Of all these 7 healthcare providers, Institut Català de la Salut (ICS) and Institut d'Assistència Sanitària (IAS) are the two main institutions, responsible for the control of 29 of the 35 ABS in total, which is a 82% of the total number of ABS in the Sanitary Region of Girona.

For this reason, we decided to perform a biotapic random sample selection as explained below. In a first stage, we made a random selection by clusters corresponding to the different ABS of the Sanitary Region of Girona. In this selection, we first grouped the different ABS from the two public health providers selected into three groups, taking into account the information provided by the administration:

- *Group 1.* ABS with <10 primary care physicians: 12 out of 29 ABS (41% of the total)
- *Group 2.* ABS with between 10 and 15 primary care physicians: 7 out of 29 ABS (17%)
- *Group 3.* ABS with >15 primary care physicians: 10 out of 29 ABS (38%)

Prior to randomization, we sorted out by alphabetical order the names of the different ABS. After that, we proceeded to randomize each group taking into account the number of primary care physicians of each ABS in relation with the total, as follows, by using the statistical programme EPIDAT 4.0:

- *Group 1.* 81 primary care physicians (23% of the total number)
- *Group 2.* 72 primary care physicians (21% of the total number)
- *Group 3.* 194 primary care physicians (56% of the total number)

Lately and taking into account the sample size (165 primary care physicians), we randomly selected a 23% of primary care physicians of group 1 (38 primary care physicians, that corresponds to 8 ABS), 21% of primary care physicians of group 2 (35 primary care physicians, that corresponds to 3 ABS) and 56% of primary care physicians of group 3 (92 primary care physicians, that corresponds to 5 ABS).

In a second stage, we did a convenience sampling, involving all the primary care physicians attending the weekly meeting in the ABS and without informing them previously about the study, in order to avoid the possible number of dropouts.

#### **7.4. Sample size**

For calculating the sample size, we used the application EPIDAT 4.0 that is a free statistical and epidemiological program for data analysis. Accepting an alpha risk of 0.95 for a precision of +/- 0.07 units in a two-sided test for an estimated proportion of 0.7, **165** subjects randomly selected from the whole population are required assuming that such population is infinite. A replacement rate of 20% was anticipated.

#### **7.5. Variables**

Taking into account the main aims of this study, we defined below the different variables that are going to be studied through the use of a questionnaire that is explained in detail later in the protocol (Annex 1)

##### **7.5.1. Dependent variable**

The dependent variable in this study is the correct antibiotic treatment in cases of acute pharyngitis caused by group A streptococci, which is a binary qualitative variable. According to the guideline published in 2012 by the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) antibiotics should not be used in patients

with Centor criteria under 2, in order to relieve symptoms. In more severe acute pharyngitis symptoms (Centor criteria 3-4) antibiotics should be considered and primary care physician should discuss with the patient about its limited benefits and its possible side effects <sup>(9)</sup>.

For the definition of this variable, as explained, we used the ESCMID guideline published in 2012 because although, there is a manual about infections in primary care published by the Sociedad Española de Medicina de Familia y Comunitaria (semFYC), this is very unspecific and it is not updated <sup>(20)</sup>. For this reason, we considered the ESCMID guideline as the closest to our publications, as well as the most updated of all and one of the most cited ones, ruling out other guidelines as the IDSA or NICE <sup>(13, 23)</sup>.

To analyse this binary qualitative variable, we included two clinical cases in the questionnaire, in order to study if primary care physicians prescribe the correct treatment depending on the Centor criteria, as is stipulated in the ESCMID guideline. The first clinical case (Annex 1. Clinical case 1) presents a patient with 2 out of 4 Centor criteria in which is not recommended to prescribe antibiotics but NSAIDs (correct answer B). The second clinical case (Annex 1. Clinical case 2) presents a patient with 3 out of 4 Centor criteria in which it is appropriated to prescribe antibiotics, due to the high suspicion of streptococcal infection but not to the inquietude for possible complications (correct answer A). We will consider a correct antibiotic prescription when the answers to the clinical cases are B in the first case and A in the second case. On the other hand, we will consider an incorrect antibiotic prescription when the answers are neither B nor A, respectively.

### **7.5.2. Independent variables**

With the independent variables, we decided to group them into 4 groups as explained below, to facilitate later interpretation:

a) Variables related with professionals personal characteristics: in this group there are six variables:

- *Age*: is a discrete quantitative variable that we will analyse in the questionnaire by using an open question in 1-year intervals (date of birth).
- *Gender*: is a binary qualitative variable that we will analyse in the questionnaire by using a closed question with two options: man/woman.

- *Years of professional practice*: is a discrete quantitative variable that we will analyse in the questionnaire by using an open question in 1-year intervals (years of professional practice).
- *Specialized training via MIR*: is a binary qualitative variable that we will analyse in the questionnaire by using a closed question with two options: yes/no
- *Medical speciality*: is a politomic qualitative variable that we will analyse in the questionnaire by using a closed question with three options being the last one an open answer: primary care physician/internist/other.
- *Teaching tutor*: is a binary qualitative variable that we will analyse in the questionnaire by using a closed question with two options: yes/no

b) Variables related with professionals workplace: in this group there are three variables:

- *Inhabitants number of the workplace town*: is politomic qualitative variable that we will analyse in the questionnaire by using a closed question with four options: <2000/2000-10000/10000-20000/>20000.
- *Care burden of workplace*: is a discrete quantitative variable that we will analyse in the questionnaire by using a closed question with three options: less than 20 visits per day/between 20 and 30 visits per day/more than 30 visits per day.
- *Rapid antigen test availability in workplace*: is a binary qualitative variable that we will analyse in the questionnaire by using a closed question with two options: yes/no.

c) Variables related with professionals knowledge: in this group there are two variables:

- *Self-training*: is a discrete quantitative variable that pretends to analyse the weekly hours that the professionals use to read guidelines and articles. We will analyse it with a closed question with three options: less than 1-hour weekly/between 1 and 3 hours weekly/ more than 3 hours weekly.

- *Knowledge about the correct use of rapid antigen test (RAT):* is a binary qualitative variable. According to the guideline published in 2012 by the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) RAT test may be performed in patients with 3 or 4 Centor criteria <sup>(9)</sup>.

For this reason and in order to analyse this variable, we will include a clinical case to know if primary care physicians use RAT correctly. The clinical case (Annex 1. Clinical case 3) presents a patient with 3 over 4 Centor criteria in which is recommended to perform the RAT (correct answer A). We will consider a correct use of the RAT when the answer to the clinical case is A. On the other hand, we will consider a less correct procedure when the answers are B or C, respectively.

d) Variables related with professionals attitudes: in this group there are two variables:

- *Management of uncertainty:* as mentioned earlier in the introduction, the risk of complications is very low and there is little scientific evidence that the Centor criteria could be useful to predict possible complications. The ESCMID guideline, as we have said, recommends the prescription of antibiotics when the patient presents 3 or more Centor criteria, and it does not modify the recommendations taking into account the uncertainty due to complications.

In order to analyse this binary qualitative variable, we will use two of the clinical cases used before (Annex 1. Clinical case 1 and 2), in which one of the possible options tries to analyse this uncertainty and the derived incorrect prescription, facing the possibility of complications (correct answers B and A, respectively). We have also created another clinical case (Annex 1. Clinical case 4), that presents a patient who, although does not need antibiotics, insist in receiving it (correct answer A). We will consider a correct antibiotic prescription when the answers to the clinical cases are B in the first case, A in the second case and A in the fourth case. On the other hand, we will consider an incorrect antibiotic prescription when the answers are neither B, A nor A, respectively.

- *Management of pressure exerted by patients:* is a binary qualitative variable that pretends to study if primary care professionals are influenced to prescribe antibiotics due to the pressure exerted by patients, as some studies glimpse. In order to analyse this variable we will use again a clinical case (Annex 1. Clinical case 4) that

presents a patient who, although does not need antibiotics, insist in receiving it (correct answer A). We will consider a correct antibiotic prescription when the answer to the clinical case is A. On the other hand, we will consider an incorrect antibiotic prescription when the answers are B or C, respectively.

Finally, we summarized all the variables in the table below:

Variables			Brief description
<b>Dependent</b>	Correct antibiotic treatment in acute pharyngitis caused by group A streptococci		Binary qualitative variable (correct/incorrect)
<b>Independents</b>	Related with personal characteristics	Age	Discrete quantitative variable (date of birth)
		Gender	Binary qualitative variable (man/woman)
		Years of professional practice	Discrete quantitative variable (years of professional practice)
		Specialized training via MIR	Binary qualitative variable (yes/no)
		Medical speciality	Politomic qualitative variable (primary care physician/internist/others)
		Teaching tutor	Binary qualitative variable (yes/no)
	Related with workplace characteristics	Inhabitants number of the workplace town	Politomic qualitative variable (<2000/2000-10000/10000-20000/>20000)
		Care burden of workplace	Discrete quantitative variable (less than 20 visits per day/between 20 and 30/more than 30 visits per day)
		RAT availability in workplace	Binary qualitative variable (yes/no)
	Related with professionals knowledge	Self-training	Discrete quantitative variable (less than 1-hour weekly/ between 1 and 3/more than 3 weekly)
		Knowledge about correct RAT use	Binary qualitative variable (correct/less correct)
	Related with professionals attitudes	Management of uncertainty	Binary qualitative variable (correct/incorrect)
		Management of pressure exerted by patients	Binary qualitative variable (correct/incorrect)

### **7.6. Measure instruments**

For studying the different variables in our sample selection, we created a questionnaire as the main tool (Annex 1). Before designing it, we did an extensive review of bibliography in different databases such as MEDLINE or Cochrane Library using the following descriptors: [acute pharyngitis, group A streptococci, variables influencing physicians, questionnaire, primary care, influencing factors, perceptions and attitudes].

After this review we found two interesting studies with similar aims to our study. The first was a study that was carried out in a China and published in May 2013. This study had as main aim to find the patterns and factors influencing prescription in physicians <sup>(27)</sup>. The other study that we used as a reference was a French one that was published in March 2012 and that tried to determine which were the major variables that influence physicians to the realization of rapid antigen test for the detection of group A streptococci acute pharyngitis <sup>(25)</sup>.

Although based in these two studies, anyone includes in the corresponding article the same questionnaires with the exact same questions. We just found the analysed variables as well as the results derived from these. For this reason, we formulated the questions to study these variables and we added other variables that we considered relevant in the final therapeutically decision taken by the physician, taking also into account the opinion of some primary care professionals. It is important to say that, a validation by the translation and back-translation method has not been done, procedure that should have been done if the original questionnaires were found.

The questionnaire was written in Catalan and Spanish (Annex 1), in order to avoid incorrect interpretation of the questions due to language discrepancies and thus cover more professionals. Also, a pre-test was done in order to evaluate the questionnaire. To do this, we gave the questionnaire to three primary care professionals in order to determine the time needed as well as the type of answers obtained.

### **7.7. Data collection**

For data collection we will contact with the directors of the different ABS selected by telephone or go directly to the centre, in order to inform them about the objectives of the study and ask for their collaboration. We will agree with them, to set aside 30 minutes a day coinciding with a weekly meeting and we will ask the directors not to inform the participants that this study will be done, in order to decrease the possible number of

dropouts. However, there is a possibility that the director of the selected ABS does not want to participate in the study. If this happens, we will select the next ABS according to the alphabetical list.

On the agreed day, a member of the research team will go to the ABS and will inform to the primary care professionals present in the weekly meeting about the aims of the study, as well as about the procedure for answering the questionnaires and ethical aspects of the study. Finally, we will give 30 minutes time to the professionals for answering the questionnaire individually.

Once all the questionnaires are answered, we will introduce all the collected data in a database manager such as Microsoft Access using the correct security filters.



## 8. Statistical analysis

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To perform the statistical analysis of the obtained data through the study, we will first create a descriptive table with the different variables. For discrete quantitative variables we will use the median and percentiles, while for the qualitative variables (binary and politomic) we will use percentages and confidence interval (CI). Furthermore, we will evaluate the normal distribution of the quantitative variables by using the Kolmogórov-Smirnov test.

Once the description of the variables is done, we will do a bivariate statistical study, in which we will compare the different independent variables (quantitative and qualitative) with the dependent variable. In order to facilitate the statistical analysis we will regroup discrete quantitative variables according to the answers on the questionnaire.

Lately, we will use the following statistical tests depending on the variables analysed:

- For analysing qualitative (binary and politomic) independent variables with the dependent one, we will use chi-squared.
- For analysing discrete quantitative independent variables with the dependent one, we will use a t-student test if there are two groups to compare and an analysis of variance (ANOVA) if there are more than two groups to compare. For not normal distributions we will use non-parametric tests.

Finally we will do a multivariate analysis by stages such a logistic regression, in which we will introduce the different variables step by step:

1. We will select the variables with P value statistical significance of  $<0,10$
2. We will select the variable which, although have not a relevance, the research team consider that could be transcendent for the final results
3. We will select the variables which we have found to be relevant in the literature

To perform this analysis, we will use IBM SPSS Statistics 23.0 statistical program. The results will be presented with odds ratio (OR) and confidence interval (CI).

## **9. Ethical considerations**

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Some ethical procedures must be done before carrying out this study, such as presenting the research protocol to the Comitè Ètic d'Investigació Clínica (CEIC) de l'IDIAP Jordi Gol, which is the main ethical committee of clinical research in primary care in Catalonia.

This study will be carried out in accordance with the ethical principles for medical research involving human subjects established by Declaration of Helsinki, protecting the privacy of all the participants as well as the confidentiality of their personal information. Furthermore, it will also comply the Ley Orgánica 15/1999 of 13<sup>th</sup> of December or “Personal data protection”, whose main aim is to guarantee and protect freedom and fundamental rights of physical people.

Finally, we will provide an information document where the study will be explained to all the participants as well as an informed consent (Annex 2), before giving them the questionnaire.

## **10. Limitations**

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Regarding the limitations of this study, we considered basically three explained below:

1. The sample refers to the Health Region of Girona, which means it could not be accurately extrapolated to other sanitary regions or communities. However, the procedure used to select the sample, including urban, semi-rural and rural areas as well as the use of two huge and different public health care providers, increases its reliability and capacity to estimate conclusions for the entire population.
2. The director is the first person that has to accept to carry out the study, and it is possible that some of them do not want to take part in it. If this happens, we will select the next ABS according to the alphabetical list, as explained in the methodology section.
3. Taking into account that participation of the primary care physicians in the study is voluntary, it is possible that some of the professionals that were included in the sample do not want to fill out the questionnaire. For this reason, we estimated a 20% of dropouts in the sample size.
4. Being a questionnaire in which some knowledge and attitudes are analysed, this can lead to an information bias, in which participants could answer not what they really think but another answer in order to give a good impression about themselves. This is an inherent limitation of these studies.

## 11. Work plan

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This study has been designed in 4 stages, as it is explained below:

1. **Coordination stage** (2 months): In this stage we will do a first informative meeting with all the research team to explain clearly the objectives of the study and the concrete procedure that must be performed during the fieldwork. A schedule will be done to facilitate the work to the research team and to distribute the main tasks.

Furthermore we will have weekly telematics meetings as well as monthly face-to-face meetings, till the end of the study and in order to solve problems that can appear

2. **Fieldwork** (4 months): In this stage, some of the members of the research team will be the main responsible of contacting with the ABS directors with the aim of explaining the hole project and in order to ask for help, as we have explained before. The same members will be also the responsible to attend on the agreed day to the ABS and explain the main objectives of the study, as well as the procedure to do the questionnaire and other important questions, to the participant professionals. The questionnaires, information document and informed consent will be distributed, and all the questions that the participants may have, will be solved.

Lately, when all the questionnaires will be done, some members of the research team will have to transfer the information to the created database.

3. **Statistical analysis and publication of the results** (4 months): We will hire statistical support from Sistema d'informació pel Desenvolupament de la Investigació a l'Atenció Primària (SIDIAP), in order to analyse all the collected data. They will first conduct a descriptive study of all the different variables, and lately, they will do a bivariate analysis of the variables, followed by a multivariate analysis by using a logistic regression model.

Finally, some articles will be written according to the results of the study, in order to publish this study in a scientific journal.

We created also a chronogram, that include the different tasks and personal who will do it:

Task	Personal	Jan-Feb 2014	Mar-Apr 2014	May-Jun 2014	Jul-Aug 2014	Sep-Oct 2014
Coordination stage	All the team					
Contact with the ABS directors	APF, RGR, GCT					
Distribution of questionnaires	APF, RGR, GCT					
Statistical analysis	Statistical support					
Evaluation and publication of the results	All the team					

*Team:* Anna Pujol Flores (APF), Ramon Gómez Ros (RGR), Gabriel Coll de Tuero (GCT), Antonio Rodriguez Poncelas (ARP)

Finally, the research team has taken into account two other stages that we should consider. These stages are explained below:

1. **Dissemination plan:** if the results of the study concluded that, there are variables influencing the prescription of antibiotics in acute pharyngitis caused by group A streptococci, we will try to disseminate our study by sending the results to the Sanitary Region of Girona manager. We will attend also the XXXVII Congreso de la Sociedad Española de Medicina de Familia y Comunitaria (semFYC) that will be celebrated in Gran Canaria from 12 to 14 of June 2014, in order to present the results and try to inform the professionals about which changes could be done in order to improve the treatment with antibiotics in acute pharyngitis caused by group A streptococci and decrease the secondary effects and resistances due to them.
2. **Further research:** further studies, taking into account the results of the study, should be done, for example in order to write a national guideline, which, it does not exist nowadays.

## 12. Budget

The research team will carry out all the tasks related with the determination and extraction of the sample, as well as, the contact with the different ABS directors, the distribution and explanation of the questionnaires to the primary care professionals, and the systematic archive of the data obtained. However, we will hire statistics support and assess (done by SIDIAP) in order to execute statistical analysis of the obtained results. The estimated budget for statistical support is 700€ (35€ per hour, assuming 20 hours).

We also included expenses in relation to transport, which will be used to cover the visits that will be done by the research team to the ABS. They will firstly meet the directors and lately will pass the questionnaires. For this reason, we calculated a price of 0,7€ per kilometre, which estimating a total distance of 571km is 400€ total. Translation and Open Acces publication expenses were also budgeted, with a total price of 1000€

Finally we calculated the costs of attending to the XXXVII Congreso de la Sociedad Española de Medicina de Familia y Comunitaria (semFYC) that will be celebrated in Gran Canaria from 12 to 14 of June 2014. For this congress we budgeted 1200€, which includes registration, accommodation and subsistence.

Requested budget	
Expenses	Euros
1. Staff expenses	
• Statistical support and asses (SIDIAP)	700€
2. Executive and management expenses	
• Meetings in the different ABS	400€
• Translation and Open Access publication	1000€
3. Travel and subsistence	
• Attendance to XXXVII Congreso semFYC	1200€
<b>TOTAL</b>	<b>3300€</b>

### **13. Means available to develop the study**

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In order to develop this study, we have access to an office in the Unitat de Recerca del Institut d'Assistència Sanitària in Hospital de Santa Caterina, as well as computers and useful software (EPIDAT 4.0, Microsoft Access and IBM SPSS Statistics 23.0) for developing the different processes of the study. Furthermore, each one of the members of the research team have means of transportation, which allows them to move everywhere for the different meetings.

The huge professional experience of the research team, allows us to have many contacts that will be useful for developing the project, such as access to epidemiological data or contact with the different ABS directors.

#### **14. Project impact on the National Health Service**

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In relation with the impact that this project may have on the National Health Service, we highlight the main benefits that the health managers and politicians may have. If the variables studied are found to be relevant, there will be enough data to develop intervention programs in primary care centres, with the main aim of improving the professional's skills as well as the patients care. Furthermore, improvements in this topic could help to decrease the sanitary expenses derived from antibiotic treatments, such as secondary effects or antibiotic resistances.

Another of the possible beneficiaries of the conclusions of this study may be the educative community. If the study shows that there are certain variables that are currently influencing the doctors, some new objectives can be introduced in the teaching plan of different medicine faculties, in order to improve the knowledge of the future physicians.



## 15. Annexes

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### 15.1. Annex 1. Questionnaire (Catalan and Spanish)

#### 1. CATALAN

**Enquesta sobre variables principals que influeixen els metges d'atenció primària en la correcta prescripció antibiòtica en casos de faringitis aguda**

1. Data de naixement (dia/mes/any): \_\_\_\_/\_\_\_\_/\_\_\_\_
2. Sexe:
  - ☐ Dona
  - ☐ Home
3. Anys d'exercici professional: \_\_\_\_\_
4. Formació especialitzada via MIR:
  - ☐ SI
  - ☐ NO
5. Tipus d'especialitat:
  - ☐ Metge d'atenció primària
  - ☐ Metge internista
  - ☐ Altres: \_\_\_\_\_
6. És vostè tutor docent?
  - ☐ SI
  - ☐ NO
7. Tipus de centre on treballa actualment:
  - ☐ Urbà
  - ☐ Semiurbà
  - ☐ Rural
8. Nombre d'habitants del municipi on treballa actualment.
  - ☐ <2000
  - ☐ 2000-10000
  - ☐ 10000-20000
  - ☐ >20000
9. Disponibilitat de test ràpid antigènic (RAT) al lloc de treball:
  - ☐ SI
  - ☐ NO
10. Hores que dedica setmanalment a la lectura de guies de pràctica clínica o articles:
  - ☐ Menys d'una hora setmanal
  - ☐ Entre 1 i 3 hores setmanals
  - ☐ Més de 3 hores setmanals

A continuació se li plantegen 4 casos clínics, amb una única resposta correcta. Assenyali aquella que vostè consideri adequada mitjançant un cercle al voltant de la lletra corresponent a la resposta escollida:

**Cas clínic 1.** Acudeix a la seva consulta un pacient de 45 anys que refereix dolor de gola, des de fa 4 dies i que ha presentat febre de fins a 38,5°C en els dos últims dies. Refereix tot així com símptomes propis del refredat. A la exploració vostè observa la presència d'exsudats a nivell faringi, sense cap altre troballa destacable. Davant d'aquesta situació vostè:

- a) Sospita d'una faringitis aguda per estreptococ del grup A i decideix prescriure penicil·lina V durant 10 dies i AINEs. Recomana al pacient que acudeixi de nou a la seva consulta si el tractament proposat no resulta efectiu.
- b) Sospita de una faringitis aguda de causa vírica i decideix prescriure AINEs al pacient fins a milloria dels símptomes. Recomana al pacient que acudeixi de nou a la seva consulta si el tractament proposat no resulta efectiu.
- c) Sospita de una faringitis aguda i davant de la inquietud per possibles complicacions decideix prescriure penicil·lina V durant 10 dies. Recomana al pacient que acudeixi de nou a la seva consulta si el tractament proposat no resulta efectiu.

**Cas clínic 2.** Acudeix a la seva consulta un pacient de 45 anys que refereix dolor de gola, des de fa 4 dies i que ha presentat febre de fins a 38,5°C en els dos últims dies. No refereix tot ni símptomes propis del refredat. A la exploració vostè observa la presència d'exsudats a nivell faringi, sense cap altre troballa destacable. Davant d'aquesta situació vostè:

- a) Sospita d'una faringitis aguda per estreptococ del grup A i decideix prescriure penicil·lina V durant 10 dies i AINEs. Recomana al pacient que acudeixi de nou a la seva consulta si el tractament proposat no resulta efectiu.
- b) Sospita de una faringitis aguda de causa vírica i decideix prescriure AINEs al pacient fins a milloria dels símptomes. Recomana al pacient que acudeixi de nou a la seva consulta si el tractament proposat no resulta efectiu.
- c) Sospita de una faringitis aguda i davant de la inquietud per possibles complicacions decideix prescriure penicil·lina V durant 10 dies. Recomana al pacient que acudeixi de nou a la seva consulta si el tractament proposat no resulta efectiu.

**Cas clínic 3.** Acudeix a la seva consulta un pacient de 45 anys que refereix dolor de gola, des de fa 4 dies i que ha presentat febre de fins a 38,5°C en els dos últims dies. No refereix tos ni símptomes propis del refredat. A la exploració vostè observa la presència d'exsudats a nivell faringi, sense cap altre troballa destacable. Davant del dubte etiològic en relació a la faringitis aguda que presenta el pacient vostè:

- a) Decideix efectuar una prova antigènica ràpida (RAT) per decidir el tractament
- b) Decideix no efectuar una prova antigènica ràpida (RAT) i prescriure antibiòtics i AINEs degut a la alta sospita d'etiologia bacteriana. Recomana al pacient que acudeixi de nou a la seva consulta si el tractament proposat no resulta efectiu.
- c) Decideix no efectuar una prova antigènica ràpida (RAT) i prescriure AINEs fins a milloria dels símptomes. Recomana al pacient que acudeixi de nou a la seva consulta si el tractament proposat no resulta efectiu.

**Cas clínic 4.** Acudeix a la seva consulta un pacient de 45 anys que refereix dolor de gola, des de fa 4 dies. Refereix tos i símptomes propis del refredat. A la exploració vostè observa la presència d'exsudats a nivell faringi així com adenopaties cervicals anteriors. Vostè sospita de una faringitis aguda de causa vírica i decideix prescriure AINEs, explicant-li al pacient la seva decisió. Tot i això, el pacient no sembla estar conforme i insisteix en reclamar un antibiòtic per tractar el seu procés infecciós. Davant d'aquesta situació vostè:

- a) Intenta explicar-li al seu pacient que el antibiotic no serà efectiu degut a que vostè sospita un procés víric, per el qual aquest tractament no té utilitat.
- b) Davant de la insistència del pacient vostè decideix receptar un antibiòtic tot i que pensi que no serà útil.
- c) Davant de la insistència del pacient vostè decideix receptar un antibiòtic, tot i que pensi que no serà útil. Tot i això, la possibilitat de causa estreptocòccia és evident i les possibles complicacions derivades li fan témer una prescripció incorrecte.

## 2. SPANISH

### **Encuesta sobre variables principales que influyen a los médicos de atención primaria en la correcta prescripción antibiótica en casos de faringitis aguda**

1. Fecha de nacimiento (día/mes/año): \_\_\_\_/\_\_\_\_/\_\_\_\_
2. Sexo:
  - ☐ Mujer
  - ☐ Hombre
3. Años de ejercicio profesional: \_\_\_\_\_
4. Formación especializada vía MIR:
  - ☐ SI
  - ☐ NO
5. Tipo de especialidad:
  - ☐ Médico de atención primaria
  - ☐ Médico internista
  - ☐ Otras: \_\_\_\_\_
6. Es usted tutor docente?
  - ☐ SI
  - ☐ NO
7. Numero de habitantes del municipio donde trabaja actualmente
  - ☐ <2000
  - ☐ 2000-10000
  - ☐ 10000-20000
  - ☐ >20000
8. Carga asistencial en el lugar de trabajo:
  - ☐ <20 visitas al día
  - ☐ Entre 20-30 visitas al día
  - ☐ >30 visitas al día
9. Disponibilidad de test rápido antigénico (RAT) en el lugar de trabajo:
  - ☐ SI
  - ☐ NO
10. Horas que dedica semanalmente a la lectura de guías de práctica clínica o artículos:
  - ☐ Menos de una hora semanal
  - ☐ Entre 1 y 3 horas semanales
  - ☐ Mas de 3 horas semanales

A continuació se le plantean 4 casos clínicos, con una única respuesta correcta. Marque aquella que usted considere adecuada mediante un circulo alrededor de la letra correspondiente a la respuesta escogida:

**Caso clínico 1.** Acude a su consulta un paciente de 45 años aquejado de dolor de garganta, desde hace 4 días y que ha presentado fiebre de hasta 38,5°C en los dos últimos días. Refiere tos así como síntomas propios del resfriado. En la exploración usted observa la presencia de exudados a nivel faríngeo, sin ningún otro hallazgo destacable. Delante de tal situación usted:

- a) Sospecha de una faringitis aguda por estreptococo del grupo A y decide prescribir penicilina V durante 10 días y AINEs. Recomienda al paciente que acuda de nuevo a su consulta si el tratamiento propuesto no resulta efectivo.
- b) Sospecha de una faringitis aguda de causa vírica y decide prescribir AINEs al paciente hasta mejoría de los síntomas. Recomienda al paciente que acuda de nuevo a su consulta si el tratamiento propuesto no resulta efectivo.
- c) Sospecha de una faringitis aguda y ante la inquietud por las posibles complicaciones decide prescribir penicilina V durante 10 días y AINEs. Recomienda al paciente que acuda de nuevo a su consulta si el tratamiento propuesto no resulta efectivo.

**Caso clínico 2.** Acude a su consulta un paciente de 45 años aquejado de dolor de garganta, desde hace 4 días y que ha presentado fiebre de hasta 38,5°C en los dos últimos días. No refiere síntomas de resfriado ni otra sintomatología específica. En la exploración usted observa la presencia de exudados a nivel faríngeo, sin ningún otro hallazgo destacable. Delante de tal situación usted:

- a) Sospecha de una faringitis aguda por estreptococo del grupo A y decide prescribir penicilina V durante 10 días y AINEs. Recomienda al paciente que acuda de nuevo a su consulta si el tratamiento propuesto no resulta efectivo.
- b) Sospecha de una faringitis aguda de causa vírica y decide prescribir AINEs al paciente hasta mejoría de los síntomas. Recomienda al paciente que acuda de nuevo a su consulta si el tratamiento propuesto no resulta efectivo.
- c) Sospecha de una faringitis aguda y delante de la inquietud por las posibles complicaciones decide prescribir penicilina V durante 10 días y AINEs. Recomienda al paciente que acuda de nuevo a su consulta si el tratamiento propuesto no resulta efectivo.

**Caso clínico 3.** Acude a su consulta un paciente de 45 años aquejado de dolor de garganta, desde hace 4 días y que ha presentado fiebre de hasta 38,5°C en los dos últimos días. No refiere síntomas de resfriado ni otra sintomatología específica. En la exploración usted observa la presencia de exudados a nivel faríngeo, sin ningún otro hallazgo destacable. Delante de la duda etiológica en relación a la faringitis aguda que presenta el paciente, usted:

- a) Decide efectuar una prueba antigénica rápida (RAT) para decidir el tratamiento
- b) Decide no efectuar una prueba antigénica rápida (RAT) y recetar directamente antibióticos y AINEs debido a la alta sospecha de etiología bacteriana. Recomienda al paciente que acuda de nuevo a su consulta si el tratamiento propuesto no resulta efectivo.
- c) Decide no efectuar una prueba antigénica (RAT) rápida y prescribir AINEs al paciente hasta mejoría de los síntomas. Recomienda al paciente que acuda de nuevo a su consulta si el tratamiento propuesto no resulta efectivo.

**Caso clínico 4.** Acude a su consulta un paciente de 45 años aquejado de dolor de garganta, desde hace 4 días. Refiere tos así como síntomas propios del resfriado. En la exploración usted observa la presencia de exudados a nivel faríngeo así como adenopatías cervicales anteriores. Usted sospecha de una faringitis aguda de causa vírica y decide prescribir AINEs, explicándole al paciente su decisión. Sin embargo, este no parece conforme y insiste en reclamar un antibiótico para tratar su proceso infeccioso. Delante de tal situación usted:

- a) Intenta explicar a su paciente que el antibiótico no será efectivo debido a que usted sospecha un proceso vírico, para el cual dicho tratamiento no tiene utilidad
- b) Ante la insistencia del paciente usted decide recetar un antibiótico a pesar que piense que no será de utilidad.
- c) Ante la insistencia del paciente decide recetar un antibiótico, aunque usted crea que no será efectivo. Sin embargo la posibilidad de causa estreptocócica es evidente y las posibles complicaciones derivadas de tal infección le hacen temer una prescripción incorrecta.

## **15.2. Annex 2. Information document / Informed consent (Catalan and Spanish)**

### **1. CATALAN**

#### **Full d'informació i consentiment informat**

Agraïm la vostra col·laboració en aquest projecte de recerca en atenció primària que esta realitzant l'estudiant de 6è de Medicina de la Universitat de Girona, Anna Pujol Flores.

#### Objectius i finalitat

Aquest estudi té com a principal objectiu analitzar les principals variables que influeixen els metges d'atenció primària en la correcta prescripció en casos de faringitis agudes, amb la intenció de poder trobar eines de millora en un futur.

#### Descripció del procés

Si vostè decideix participar en el estudi l'informarem més detalladament sobre els objectius del projecte així com totes les dubtes que es pugui plantejar. Per tal de participar del estudi caldrà que durant 30 minuts respongui un qüestionari amb dades personals i unes preguntes annexes plantejades en format de cas clínic.

La participació en el estudi és totalment voluntària, i si considera que alguna de les preguntes és massa personal o no es sent còmode respondent-la, pot deixar-la en blanc.

#### Confidencialitat i protecció de les dades

Malgrat que el qüestionari és anònim, li garantim que s'adoptaran totes les mesures per mantenir la confidencialitat de les seves dades seguint la Llei Orgànica que regula la confidencialitat de les dades (Ley Orgánica 15/1999) i respectant-se també qualsevol altre que es pogués aplicar. Les dades seran utilitzades de manera exclusiva per a les finalitats d'aquest estudi

Per dur a terme el projecte que hem exposat i atenent a les disposicions legals vigents sol·licitem que completi la següent autorització. Abans i després de firmar aquest document, vostè pot fer qualsevol pregunta en relació al estudi al equip investigador.

#### Declaració del participant

Declaro que he estat correctament informat per el membre responsable del equip investigador a sota esmentat, sobre els objectius del estudi així com sobre el procés de selecció de les dades personals. També declaro que he estat informat sobre l'ús de caire

científic que es farà de les meves dades personals, així com sobre el fet que la participació en l'estudi és voluntària, que puc contestar les preguntes que jo consideri oportunes i que puc sol·licitar la retirada i eliminació de les meves dades personals en qualsevol moment del estudi. A més, he rebut una còpia d'aquest mateix document.

Nom i cognoms: \_\_\_\_\_

Firma: \_\_\_\_\_ Data i lloc: \_\_\_\_\_

Declaració del membre del equip investigador

Declaro que he informat degudament al participant del estudi.

Nom i cognoms: \_\_\_\_\_

Firma: \_\_\_\_\_ Data i lloc: \_\_\_\_\_



## 2. SPANISH

### **Hoja de información y consentimiento informado**

Agradecemos vuestra colaboración en este proyecto de investigación en atención primaria que esta realizando la estudiante de 6º de Medicina de la Universitat de Girona, Anna Pujol Flores.

#### Objetivos y finalidad

Este estudio tiene como principal objetivo analizar las principales variables que influyen a los médicos de atención primaria en la correcta prescripción en casos de faringitis aguda, con la intención de poder encontrar herramientas de mejora en un futuro.

#### Descripción del proceso

Si usted decide participar en el estudio le informaremos más detalladamente sobre los objetivos del proyecto así como sobre todas las dudas que se le puedan plantear. Para participar en el estudio será necesario que durante 30 minutos responda a un cuestionario con datos personales y unas preguntas anexas planteadas en formato de caso clínico.

La participación en el estudio es totalmente voluntaria y si considera que alguna de las preguntas es demasiado personal o no se siente cómodo respondiéndola, la puede dejar en blanco.

#### Confidencialidad y protección de los datos

A pesar de que el cuestionario es anónimo, le garantizamos que se adoptaran todas las medidas para mantener la confidencialidad de sus datos personales siguiendo la Ley Orgánica que regula la confidencialidad de los datos (Ley Orgánica 15/1999), y respetándose también cualquier otra ley que se pudiera aplicar. Sus datos serán utilizados de manera exclusiva para las finalidades de este estudio.

Para realizar el proyecto expuesto y atendiendo las disposiciones legales vigentes, solicitamos que complete la siguiente autorización. Antes y después de firmar el documento, puede realizar cualquier pregunta sobre el estudio al equipo investigador.

#### Declaración del participante

Declaro que he sido correctamente informado por el miembro responsable del equipo investigador abajo mencionado, sobre los objetivos del estudio así como sobre el proceso

de selección de los datos personales. También declaro que he estado informado sobre el uso de carácter científico que se hará con mis datos personales, así como sobre el hecho de que la participación en el estudio es voluntaria, pudiendo responder las preguntas que yo considere oportunas y pudiendo solicitar la retirada y eliminación de mis datos personales en cualquier momento del estudio. Además, he recibido una copia de este mismo documento.

Nombre y apellidos: \_\_\_\_\_

Firma: \_\_\_\_\_ Fecha y lugar: \_\_\_\_\_

Declaración del miembro del equipo investigador

Declaro que he informado debidamente al participante del estudio

Nombre y apellidos: \_\_\_\_\_

Firma: \_\_\_\_\_ Fecha y lugar: \_\_\_\_\_

